Sun Pharmaceuticals – Recall of Riomet® (metformin)

- On November 27, 2017, the FDA announced a user-level recall of two lots of Riomet (metformin) oral solution because these lots were found to be contaminated with *Scopulariopsis brevicaulis*.

Product Description	NDC	Lot number (expiration date)
Riomet (metformin) oral solution, 118 mL and 473 mL bottles	10631-206-01	A160031A (1/2018)
	10631-206-02	A160031B (1/2018)

- Riomet is indicated as an adjunct to diet and exercise to improve glycemic control in adults and children with type 2 diabetes mellitus.

- Use of the affected Riomet could potentially result in a risk of infection, especially in the immunocompromised patient. The most plausible portal of entry of this bacterium is the respiratory tract, where it may cause pneumonia, sinusitis and disseminated infections.

    - The bacterial contamination was discovered during sample preparation for the Antimicrobial Preservative Effectiveness Testing being performed as part of the 12 month stability study interval.
    - To date, there have been no reports of adverse events related to this recall.

- Anyone with an existing inventory of the recalled product should stop use and distribution and quarantine the product immediately.

- Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using the recalled Riomet.

- For general questions regarding this recall, contact Sun Pharmaceuticals at **1-800-406-7984**.